REMARKS/ARGUMENTS

Reconsideration of the rejection of the claims and allowance of the application as amended are respectfully requested. Claims 1 and 3 remain pending in this application. Claims 2 and 4 have been allowed by the Examiner.

The Examiner's 35 U.S.C. 120 rejection has been removed by the amendment of paragraph [0001] of the specification. The specification has been amended in accordance with the Examiner's suggestion to claim priority from U.S. application 10/016,826. Applicant now recognizes that 35 U.S.C. 120 more precisely requires a reference to an earlier filed application, and not merely to an issued patent based on that earlier filed application.

Applicant additionally completed a new declaration intended to specifically claim the benefit of the filing date of the 10/016,826 application, but which new declaration mistakenly recited the wrong application number [10/016,836 instead of 10/016,826]. A copy of that declaration is attached to this amendment and a new declaration claiming the benefit of the correctly numbered application will be filed later as a supplement to this amendment.

The Examiner's 35 U.S.C. 112, second paragraph, rejection of claims 1 and 3 for indefiniteness has been removed by amending those claims to correct that, as noted by the Examiner, they do not specify what to do with the obtained levels, that is, they do not specify how to make the characterization. The amendments add identical language from allowed claims 2 and 4, but without the specifically determined levels.

The Examiner's 35 USC 103(a) rejections of claims 1 and 3, presented in their best light, are based on a seeming mathematical certainty that if **a** equals **b** and **b** equals **c**, then **a** must equal **c**. The problem with this approach when applied to tests to determine the risk of disease is

that the operator is not "equals," but is better stated as "suggests." If **a** suggests **b** and **b** suggests **c**, then **a** suggests **c** if, and only if, the mechanism by which (or reason) **a** suggests **b** is the same as why **b** suggests **c**. Otherwise, there is no connection between the two. Stated in more patent terms, there must be a teaching or other suggestion to combine the equations.

Applying the analysis of the previous paragraph to claim 1, note first that *Manzi et al.* is a review article that less teaches that patients with systemic lupus erythematosus (SLA) are at an increased risk of developing cardiovascular disease than it makes a mostly unsupported observation. It then goes on to describe better techniques for testing the truth of that observation in the future. To the extent *Manzi et al.* makes any arguments in support of its observation, it's at page 180, first column, concluding that "there are a large number of potential risk factors for cardiovascular disease including traditional, inflammatory, and SLE disease-related factors." That hardly rises to a level of a convincing teaching.

In any case, the Examiner's argument is not if **a** suggests **b** and **b** suggests **c**, then **a** suggests **c** because that would require that low serum total bilirubin suggest coronary artery disease (CAD) and CAD suggest SLA, so that low serum total bilirubin suggests SLA. Instead, the Examiner's argument is that low serum total bilirubin suggests CAD, and SLA suggests CAD, so that low serum total bilirubin must suggest CAD, that is, if **a** suggests **b** and **c** suggests **b**, then **a** suggests **b**.

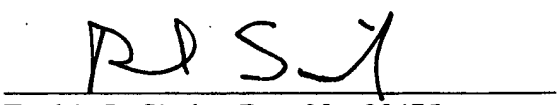
Applicant's argument in the preceding paragraph becomes somewhat moot if, if fact, there is a teaching or suggestion in the prior art that there is a similar mechanism causing both CAD and SLE. That is, if **a** suggests **b** and **a** suggests **c**, then both **b** and **c** would be expected to be often found together. *Manzi et al.*, however, makes no such showing.

Claim 3 presents similar difficulties with the Examiner's approach. First, as with SLA, *Jones et al.* teaches that psoriatic arthritis (PA) suggests CAD, not that CAD suggests (PA) which would be necessary to make the argument. Second, there is no common mechanism that suggests both CAD and PA.

While not necessary for applicant's argument, the following points help make applicant's argument more clear. One could postulate that bilirubin should be inversely related to high blood pressure or diabetes since they are both risk factors for cardiovascular disease. Yet, studies have shown that serum bilirubin concentrations are the same in individuals with diabetes and high blood pressure. SLE is characterized by increases in antinuclear antibodies; however, these antibodies have not been shown to be associated with cardiovascular disease. The prevalence of coronary heart disease is higher in men than in women, which is the opposite of the association between these forms of arthritis and coronary heart disease.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1-4, as amended, have now been shown to distinguish over the art of record. Applicant respectfully requests, therefore, that the Examiner allow the application as amended.

Respectfully submitted,



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Amendments to the Drawings

None

OIPE JC12 DEC 02 2004 PATENT & TRADEMARK OFFICE

DECLARATION FOR PATENT APPLICATION

Docket Number (Optional)
AFD 490A

As a below named inventor, I hereby declare that: ATTACHMENT

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole (or joint) inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled BILIRUBIN TESTS AS RISK PREDICTORS FOR SYSTEMIC LUPUS ERYTHEMATOSUS AND PSORIATIC ARTHRITIS, the specification of which is attached hereto unless the following box is checked:

☒ was filed on April 8, 2004 as United States Application Number or PCT International Number 10/828,526.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)			Priority Claimed
(Application Number)	Country	(Day/Month/Year Filed)	☐ Yes ☐ No
(Application Number)	Country	(Day/Month/Year Filed)	☐ Yes ☐ No

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

(Application Number)	(Filing Date)
(Application Number)	(Filing Date)

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)
10/026,836	November 9, 2001	Patented
(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name) HARVEY A. SCHWERTNER

Inventor's signature Harvey A. Schwertner [not original] Date: 19 November 2004

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☐ Additional inventors are being named on separately numbered sheets, attached hereto.